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USDOC FOR 532/OEA/HINES/GAINES
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ICE HQ FOR STRATEGIC INVESTIGATIONS
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E.O. 12958: N/A

TAGS: [ETTC](#) [ETRD](#) [BEXP](#) [IN](#)

SUBJECT: EXTRANCHECK: PRE-LICENSE CHECK: SHANTHA BIOTECHNICS
LIMITED, HYDERABAD, LICENSE D409886

REF: USDOC 0139

11. Unauthorized disclosure of the information provided below is prohibited by Section 12(c) of the Export Administration Act.

12. On February 05, 2009, Export Control Officer (ECO) Paul Cushman and FSN Shailendra Srivastava conducted a Pre-License Check (PLC) at Shantha Biotechnics Limited (SHANTHA) in Hyderabad.

13. BIS requested a PLC at SHANTHA, located at Vasantha Chambers, Fateh Maidan Road, Hyderabad. SHANTHA is listed as the ultimate consignee for an ultra filtration hollow fiber cartridge with polysulfone membrane controlled under ECCN 2B352. The license applicant is GE Healthcare Bio-Sciences Corporation (GEHBC) of Piscataway, New Jersey.

14. ECO and FSN Srivastava met with Mr. I.S. Raju, Deputy General Manager, Dr. Samir Kumar Roy, Principal Scientist, SHANTHA, and Mr. Dinesh Krishnan, Bioprocess Specialist, Mr. M. Ramesh, Sales Manager, and Mr. G. Kumar, Country Sales Leader, GEHBC, in the SHANTHA conference room.

15. SHANTHA representatives were not familiar with BIS regulations and this was the first visit by BIS officials to their facility. Raju provided a copy of the End-Use Statement and explained that SHANTHA has not yet issued the associated purchase order. GEHBC will provide SHANTHA with a sample filtration device for testing. If satisfied with its performance, SHANTHA will then issue the purchase order.

16. Roy stated that the filtration cartridge will be used to strain yeast extract proteins which serve as a growth medium for viruses during the production of various vaccines.

17. After the meeting, the BIS team was given a tour of the facility. SHANTHA employs 980 personnel. A private security force is on duty at the facility around the clock.

18. Established in 1993, Shantha Biotechnics Limited is one of the leading vaccine manufacturers in India. In 2006, SHANTHA was acquired by Merieux Alliance of France, a large multinational biotechnology company. SHANTHA's customers include the World Health Organization, UNICEF, and the Pan American Health Organization.

19. Recommendation: At the time of this visit, Shantha Biotechnics Limited appeared to be a suitable recipient of this controlled technology. SHANTHA cooperated fully with the BIS team, has a demonstrated need for the technology, and understands its responsibilities with respect to the Export Administration Regulations.
MULFORD